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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,028	05/10/2001	Fci Yang	DEX-0146	7347
26259	7590	10/02/2003	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				MYERS, CARLA J
ART UNIT		PAPER NUMBER		
		1634		

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/762,028	YANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 July 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 and 9-11 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 7-9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of group IV claims 7 with respect to SEQ ID NO: 5 in the response of July 11, 2003 is acknowledged. The traversal is on the ground(s) that a restriction requirement/lack of unity was not made in the PCT application and therefore Applicants assert that the inventions of each of the recited groups have already been examined. This is not found persuasive because unity of invention can be broken at any stage of prosecution, including when an application enters the National Stage of prosecution (see MPEP 1893.03(d)). Applicants further traverse the restriction requirement by stating that restriction is proper only if the inventions are independent or distinct and if the examination of each of the inventions together would pose a serious burden. However, these are not in fact the criteria for a restriction/lack of unity requirement in the National Stage of PCT application. As set forth in the previous Office action, the lack of unity requirement is based on the fact that the claimed invention do not share a common special technical feature. With respect to the requirement to elect a single nucleic acid, Applicants point to MPEP 803.04 and state that the MPEP indicates that a reasonable number of nucleic acids, usually 10, should be examined together in one application. Applicants assert that 5 sequences constitutes a reasonable number. This argument is not persuasive because, as stated in MPEP 803.04, up to 10 independent and distinct inventions may be examined, if undue burden is not required to examine each of these inventions together. There is no requirement that 10 distinct sequences must be examined together. In this case, it is maintained that undue burden

would be required to examine all of the nucleic acids together because the distinct members include antibodies directed to proteins having different biological properties and functions and different amino acid sequences. A search of the distinct inventions would not be co-extensive as evidenced by the requirement for searching different keywords and amino acid sequences.

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claim 7 has been examined herein to the extent that it encompasses antibodies specific to a protein encoded by a polynucleotide which comprises SEQ ID NO: 5. Furthermore, group VI (claims 8 and 9) has been rejoined with group IV and has also been examined herein

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Because claim does not recite a purity or size limitation, the claim reads on naturally occurring antibodies that bind with the polypeptide encoded by SEQ ID NO: 5. Such antibodies are products of nature and are not patentable. To overcome this rejection it is suggested that the claims be amended to include purity limitations which would distinguish the claimed compounds, as enabled by the specification, over the naturally occurring compounds. For example, this rejection may be overcome by amendment of the claims to include the terminology

"isolated" and/or to provide a description of what the claimed products are "free of" relative to that of the natural source.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are indefinite because the claims are drawn to a method of imaging lung cancer, but the claims do not recite active process steps which result in imaging lung cancer. That is, the claims recite a single step of administering an antibody but do not clarify how this step of administering an antibody results in imaging lung cancer. While the specification (see for example page 23) teaches that an increase in the expression of SEQ ID NO: 5 is correlated with the occurrence of lung cancer and teaches that the amount of labeled antibody specific to the protein encoded by SEQ ID NO: 5 can be used to diagnose the presence or absence of lung cancer *in vivo* or can be used to determine whether and to what extent the lung cancer has spread, the claims themselves do not clarify how the single step of administering an antibody results in the imaging of lung cancer.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kerlavage et al disclose an EST having GenBank Accession No. AA324584. This EST shares 94.7% identity with nucleotides 7-309 of present SEQ ID NO: 5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers  
September 26, 2003

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER